KURARAY MEDICAL INC.

Dental Material Department
3-1-6 Nihonbashi, Chuo-ku, Tokyo 103-8254, Japan
Tel : +81.3.3277.6949 Fax : +81.3.3277.6956

K022999

510(k) SUMMARY

OCT 2 4 2002

1. Submitter

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-8622, Japan
3) 1. Contact person	Koji Nishida Dental Material Department, Kuraray Medical Inc.
2. Contact person in the U.S.	Masaya Sasaki Kuraray America Inc. 101 East 52nd Street, 26th Floor New York, NY 10022 Telephone : (212)-986-2230 (Ext.115) 1-(800)-879-1676 Facsimile : (212)-867-3543
4) Date	August 25, 2002

2. Name of Device

1) Proprietary Name	CLEARFIL AP-X PLT INTRO KIT
2) Classification Name	Tooth shade resin material (21CFR 872.3690)
3) Common/Usual Name	Composite resin restorative

3. Predicate device:
The predicate devices are as follows.

1.	CLEARFIL AP-X by Kuraray Medical Inc.	(K012740)
2.	CLEARFIL SE BOND by Kuraray Medical Inc.	(K012442)

4. Description for the premarket notification
This product is classified into Tooth shade Resin Material, CFR 29 Section 872.3690, because it is a device composed of materials such as bisphenol A glycidylmethacrylate (Bis-GMA) intended to restore carious or structural defects in teeth.

5. Statement of the intended use
The intended uses of this device are as follows. They are the same as CLEARFIL AP-X manufactured by Kuraray Medical Inc.

1) Class I, II, V restorations of posterior teeth
2) Class III, IV, V restorations of anterior teeth
3) Cervical cavities or defects involving root surfaces

6. Statement of the technological characteristics and safety
This device is combination of CLEARFIL AP-X PLT and CLEARFIL SE BOND (K012442). CLEARFIL AP-X PLT is substantially same to CLEARFIL AP-X(K012740) manufactured by Kuraray Medical Inc. on the technological characteristics, chemical ingredients and safety. (K012740). Therefore the technological characteristics, chemical ingredients and safety of CLEARFIL AP-X PLT INTRO KIT are substantially equivalent as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2002

Kuraray Medical, Incorporated
C/O Ms. Masaya Sasaki
Kuraray America, Incorporated
101 East 52nd Street, 26th Floor
New York, New York 10022

Re: K022999
Trade/Device Name: CLEARFIL AP-X PLT Intro Kit
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth-Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: September 04, 2002
Received: September 09, 2002

Dear Ms. Sasaki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022999

Device Name: CLEARFIL AP-X PLT INTRO KIT

Indications for Use

CLEARFIL AP-X PLT INTRO KIT is indicated for the following applications:

1) Class I, II, V restorations of posterior teeth
2) Class III, IV, V restorations of anterior teeth
3) Cervical cavities or defects involving root surfaces

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____

(Optional Format 1-2-96)

A Sheets DDS for Dr Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K022999